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WO 2004/032958 A1

(54) Title: POLYPEPTIDE-VACCINES FOR BROAD PROTECTION AGAINST HYPERVIRULENT MENINGOCOCCAL LINEAGES

(57) Abstract: A small number of defined antigens can provide broad protection against meningococcal infection, and the invention provides a composition which, after administration to a subject, is able to induce an antibody response in that subject, wherein the antibody response is bactericidal against two or three of hypervirulent lineages A4, ET 5 and lineage 3 of *N.meningitidis* serogroup B. Rather than consisting of a single antigen, the composition comprises a mixture of 10 or fewer purified antigens, and should not include complex or undefined mixtures of antigens such as outer membrane vesicles. Five protein antigens are used in particular: (1) a 'NadA' protein; (2) a '741' protein; (3) a '936' protein; (4) a '953' protein; and (5) a '287' protein.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB 03/04848

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K39/095 C07K14/22 A61P31/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, BIOSIS, WPI Data, MEDLINE, PAJ, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01 64920 A (COMANDUCCI MAURIZIO ;PIZZA MARIAGRAZIA (IT); CHIRON SPA (IT); GALE) 7 September 2001 (2001-09-07) cited in the application page 24 ---	1-3,16, 17,19-29
X	WO 01 64922 A (COMANDUCCI MAURIZIO ;PIZZA MARIAGRAZIA (IT); CHIRON SPA (IT); GALE) 7 September 2001 (2001-09-07) cited in the application page 37 page 54 ---	1-3,16, 17,19-29
P,X	WO 03 020756 A (PIZZA MARIAGRAZIA ;CHIRON SPA (IT)) 13 March 2003 (2003-03-13) cited in the application page 8 ---	1-3, 16-29

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority, claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

8 document member of the same patent family

Date of the actual completion of the international search

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International Application No
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C(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P, X	WO 03 010194 A (COMANDUCCI MAURIZIO ;ARICO MARIA (IT); CHIRON SPA (IT)) 6 February 2003 (2003-02-06) cited in the application page 13, line 13 ----	1,3,28, 29
X	COMANDUCCI MAURIZIO ET AL: "NadA, a novel vaccine candidate of <i>Neisseria meningitidis</i> " JOURNAL OF EXPERIMENTAL MEDICINE, vol. 195, no. 11, 3 June 2002 (2002-06-03), pages 1445-1454, XP002272871 ISSN: 0022-1007 cited in the application page 1446 ----	30
A	GRIFANTINI RENATA ET AL: "Previously unrecognized vaccine candidates against group B meningococcus identified by DNA microarrays" NATURE BIOTECHNOLOGY, vol. 20, no. 9, September 2002 (2002-09), pages 914-921, XP002272872 ISSN: 1087-0156 the whole document -----	1-31

INTERNATIONAL SEARCH REPORT

Internat'l application No.
PCT/IB 03/04848

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:
Although claim 28 is to a method involving a surgical step to be carried out on the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.
 No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB 03/04848

Patent document cited in search report		Publication date		Patent family member(s)	Publication date
WO 0164920	A	07-09-2001		AU 3249200 A AU 3947801 A AU 3948801 A BR 0010361 A CA 2371032 A1 CA 2400562 A1 CA 2400570 A1 CN 1359426 T CN 1426471 T CN 1426473 T EP 1185691 A1 EP 1261723 A2 EP 1259627 A2 WO 0164920 A2 WO 0164922 A2 JP 2003527079 T JP 2003525049 T JP 2003525050 T WO 0066791 A1	17-11-2000 12-09-2001 12-09-2001 10-06-2003 09-11-2000 07-09-2001 07-09-2001 17-07-2002 25-06-2003 25-06-2003 13-03-2002 04-12-2002 27-11-2002 07-09-2001 07-09-2001 16-09-2003 26-08-2003 26-08-2003 09-11-2000
WO 0164922	A	07-09-2001		AU 3249200 A AU 3947801 A AU 3948801 A BR 0010361 A CA 2371032 A1 CA 2400562 A1 CA 2400570 A1 CN 1359426 T CN 1426471 T CN 1426473 T EP 1185691 A1 EP 1261723 A2 EP 1259627 A2 WO 0164920 A2 WO 0164922 A2 JP 2003527079 T JP 2003525049 T JP 2003525050 T WO 0066791 A1	17-11-2000 12-09-2001 12-09-2001 10-06-2003 09-11-2000 07-09-2001 07-09-2001 17-07-2002 25-06-2003 25-06-2003 13-03-2002 04-12-2002 27-11-2002 07-09-2001 07-09-2001 16-09-2003 26-08-2003 26-08-2003 09-11-2000
WO 03020756	A	13-03-2003		WO 03010194 A2 WO 03020756 A2	06-02-2003 13-03-2003
WO 03010194	A	06-02-2003		WO 03010194 A2 WO 03020756 A2	06-02-2003 13-03-2003